Bacterial ID Systems
Quality Control and Regulations

An FDA Perspective

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Objectives

- Regulatory History of ID systems
- Exemptions/Limitations
- What we look for
  - Intended Use
  - Technological Characteristics
  - Identifications directly from clinical material

Regulatory Background

- Federal Food, Drug, and Cosmetic Act of 1938 (The Act)
- Medical Device Amendments of May 28, 1976 – classified all existing IVDs
- Clinical Laboratory Improvement Act (CLIA) 1988
- Safe Medical Devices Act of 1990
- FDA Modernization Act (FDAMA) of 1997

Classification

- Class I Device
  - General Controls sufficient
  - Test result does not present unreasonable risk of injury
- Class II Device
  - Special Controls Needed
- Class III
  - Test results present a risk of misdiagnosis that could cause serious injury

Bacterial Identification Systems

- Regulated under 21 CFR Section 866.2660
- Microorganism differentiation and identification device
- Product Codes:
  - LQM - Gram Negative ID Panel
  - LQL - Gram Positive ID Panel

Bacterial Identification System Description

- Consists of one or more components such as, differential culture media, biochemical reagents, and paper discs or paper strips impregnated with test reagents, usually contained in compartments, intended for use to differentiate and identify selected microorganisms

Bacterial ID Systems
Regulatory History

- FRN Nov. 9, 1982, Class I. General controls sufficient
- FRN Nov. 12, 1998, Proposed rule Class I devices Exempt from 510(k)
- FRN Jan. 14, 2000 Final Rule: device exempt from premarket notification procedures in subpart E of part 807 of 21 CFR.

Regulatory History
Exemptions from Limitations

- Comments: FDA should not exempt ID systems that identify microorganisms directly from clinical specimens.
- FDA concurred: Limitation to Exemptions were included which include identifying or inferring identity directly from clinical material.

510(k) Exempted

- Explanation: FDA Modernization Act Nov.21,1997, Section 501
  - This section provides that Class I devices not intended for substantial important use in preventing impairment of human health or not presenting a potential reasonable risk of illness or injury shall be exempted

Limitations to Exemption

Device changes which may affect safety

- New Intended Use, differs from currently marketed tests
- New or significantly different technology from currently marketed tests
- An *in vitro* diagnostic intended for
  - Surrogate markers for life-threatening diseases, e.g. hepatitis, tuberculosis
  - Identification or inferring identification directly from clinical specimens

Exempted Devices
Regulatory Oversight

- Subject to Registration & Listing
- Subject to Quality Systems Regulations
  - Inspections
- Subject to device adverse event reporting (MDRs – MedWatch)
  - Recalls
  - Injunctions, seizures

Clinical Study Issues

- Data to support intended use
- Validation of design and software
- Studies performed with QC

Clinical Study issues (con't)
Quality Controls

- FDA expectation is that QC system be transparently described.

Clinical Study issues (con't)
Quality Controls

- FDA does not mandate lab specific practices because of heterogeneity in practices.

IVD Challenges

- Monitoring new ID systems for any emerging infectious disease
- Defining performance yardsticks for direct detection systems
- Obtaining relevant isolates for evaluation, and optimization of database
- Combined challenge: public health, infection control, laboratories, industry and FDA

Package Inserts

- Conform to 21 CFR 809.10
- Clear Intended Use/Indications Statement
- Performance Characteristics represents studies
- Appropriate Warnings, Precautions, Limitations
- Quality Control Section included
- Interpretation of Results

Summary

- Legal mandate to regulate products used on human specimens to diagnose illness or health
- Manufacturers determine if device requires a 510(k) or are exempted
- FDA calls for 510(k) when we become aware and consider that device meets Limitations to Exemption
- Package insert does not indicate which devices are exempt and not evaluated by FDA
- Quality Control section should indicate that QC testing should confirm to local, state or federal requirements